PURE BIOSCIENCE Form 10-Q December 10, 2009

## UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

#### FORM 10-Q

ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED OCTOBER 31, 2009

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934

Commission File Number 0-21019

# PURE Bioscience (Exact name of registrant as specified in its charter)

California
(State or other jurisdiction of incorporation or organization)

33-0530289 (I.R.S. Employer Identification No.)

1725 Gillespie Way
El Cajon, California 92020
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (619) 596-8600

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o Accelerated filer ý Non-accelerated filer o Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No  $\acute{y}$ 

As of December 9, 2009, there were 34,333,288 shares of the registrant's common stock, no par value, outstanding.

## **PURE Bioscience**

## FORM 10-Q

for the Quarterly Period Ended October 31, 2009

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## PURE Bioscience

## CONSOLIDATED BALANCE SHEETS

ASSETS	(Unaudited) October 31, 2009	July 31, 2009
Current Assets		
Cash and cash equivalents	\$5,600,293	\$4,213,744
Accounts receivable, net of allowance for doubtful accounts	\$0,000, <b>2</b> 50	Ψ 1,210,7 1 1
of \$0 at October 31, 2009 and \$0 at July 31, 2009	145,224	143,031
Inventories, net	430,026	421,655
Prepaid expenses	29,820	69,317
	_,,,_,	03,027
Total current assets	6,205,363	4,847,747
Total property, plant and equipment, net	823,242	856,504
Patents	1,959,378	1,944,701
Total assets	\$8,987,983	\$7,648,952
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	\$416,296	\$368,418
Accrued liabilities	146,840	192,348
Customer deposits	9,400	-
Taxes payable	-	2,400
Total current liabilities	572,536	563,166
Deferred rent	19,541	19,351
Total liabilities	592,077	582,517
0. 11 11 15 2		
Stockholders' Equity		
Preferred Stock, no par value:		
5,000,000 shares authorized, no shares issued	-	-
Class A common stock, no par value:		
50,000,000 shares authorized		
34,126,148 issued and outstanding at October 31, 2009, and	40 494 572	29 409 004
32,307,966 issued and outstanding at July 31, 2009	40,484,572	38,498,904 4,566,024
Additional Paid-In Capital Warrants:	4,795,951	4,300,024
2,229,906 issued and outstanding at October 31, 2009, and		
1,411,725 issued and outstanding at October 31, 2009, and	3,326,753	2,501,682
Accumulated deficit	(40,211,370	(38,500,175)
Accumulated deficit	(+0,211,370	(30,300,173 )

Total stockholders' equity	8,395,906	7,066,435
Total liabilities and stockholders' equity	\$8,987,983	\$7,648,952

The accompanying notes are an integral part of the consolidated financial statements

## **PURE Bioscience**

# CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

For the Three Months Ended October 31, 2009 2008 Net revenues \$221,871 \$110,621 Cost of sales 80,157 59,812 Gross profit 50,809 141,714 219,938 151,192 Selling expenses General and administrative expenses 1,184,579 1,262,435 Research and development 286,962 457,868 Total operating expenses 1,862,385 1,700,589 Loss from operations (1,720,671)(1,649,780)Other income and (expense): Interest income 9,476 8,763 Other 35,701 Total other income (expense) 9,476 44,464 Net loss before income taxes (1,711,195 (1,605,316 Income tax provision Net loss \$(1,711,195 ) \$(1,605,316 Net loss per common share, basic and diluted \$(0.05 ) \$(0.05 Weighted average common shares used in computing basic and diluted net loss per common share 33,454,211 29,668,089

The accompanying notes are an integral part of the consolidated financial statements

## PURE Bioscience

# CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

For the Three Months Ended October 31, 2009 2008

# Cash flows from operating activities:

Net loss	\$(1,711,195	)	\$(1,605,316	)
Adjustments to reconcile net loss to net cash				
used in operating activities:				
Amortization and depreciation	115,245		108,397	
Stock-based compensation	257,433		86,991	
Changes in assets and liabilities:				
Accounts receivable	(2,193	)	(8,072	)
Prepaid expense	39,497		30,377	
Inventories	(8,371	)	(61,979	)
Deferred rent	190		1,866	
Deferred revenue	-		(3,993	)
Customer deposits	9,400		-	
Accounts payable and accrued liabilities	2,370		(141,653	)
Income tax payable	(2,400	)	-	
Net cash (used) in operating activities	(1,300,024	)	(1,593,382	)
Cash flows from investing activities				
Investment in patents	(58,940	)	(19,663	)
Purchase of property, plant and equipment	(37,720	)	(40,936	)
Purchases of short-term investments	-	,	(4,076,992	)
Sales of short-term investments	_		4,589,298	,
Successful investments			1,505,250	
Net cash provided by (used) in investing activities	(96,660	)	451,707	
Cash flows from financing activities				
	2.702.222			
Net proceeds from the sale of common stock	2,783,233		165.070	
Proceeds from exercise of stock options and warrants	-		165,079	
Net cash provided by financing activities	2,783,233		165,079	
Net increase (decrease) in cash and cash equivalents	1,386,549		(976,596	)
The mercase (decrease) in cash and cash equivalents	1,500,57		()10,570	,
Cash and cash equivalents at beginning of period	4,213,744		2,024,400	

Cash and cash equivalents at end of period

\$5,600,293

\$1,047,804

The accompanying notes are an integral part of the consolidated financial statements

Notes to Consolidated Financial Statements (Unaudited)

#### Note 1. Basis of Presentation

PURE Bioscience (sometimes referred to herein as the "Company" or "we") was incorporated in the state of California on August 24, 1992. The accompanying unaudited financial statements include the consolidated accounts of PURE Bioscience and its subsidiary, ETIH2O Corporation, a Nevada corporation. All inter-company balances and transactions have been eliminated.

The financial statements included herein have been prepared by PURE Bioscience without audit, in accordance with the instructions to Securities and Exchange Commission ("SEC") Form 10-Q and Article 10 of Regulation S-X. Certain information and footnote disclosures normally included in the financial statements prepared in accordance with U.S. generally accepted accounting principles ("GAAP"), have been condensed or omitted as allowed by such rules and regulations, however we believe that the accompanying unaudited financial statements contain all adjustments (including normal recurring adjustments) necessary to present fairly the financial condition, results of operations and cash flows for the periods presented. These unaudited consolidated financial statements presented herein should be read in conjunction with our audited financial statements for our most recently completed fiscal year ended July 31, 2009, and their accompanying notes, as filed with the SEC in our 10-K on October 13, 2009.

The preparation of the consolidated financial statements requires management to make estimates and assumptions that affect the amounts reported in the statements and accompanying notes, and actual results could differ materially from those estimates. The results of operations for the three month period ended October 31, 2009 (the "First Quarter") are not necessarily indicative of the results of operations for the full year, or any future periods.

## Note 2. Nature of Business and Summary of Significant Accounting Policies

#### Concentration of Credit Risk

As of October 31, 2009 and July 31, 2009, all cash deposits were invested in either U.S. FDIC insured bank accounts or institutional money market mutual funds investing in A-1 (S&P) or Prime-1 (Moody's).

At October 31, 2009, \$4,985,200 of our cash and cash equivalents were maintained at three separate major financial institutions in the United States in accounts that are insured by the Federal Deposit Insurance Corporation ("FDIC") up to \$100,000. Effective October 3, 2008, the Emergency Economic Stabilization Act of 2008 raised the FDIC deposit coverage limits to \$250,000 per owner from \$100,000 per owner. The enhanced limits are currently available through December 31, 2009.

Also at October 31, 2009, \$614,500 of our cash and cash equivalents were held in accounts maintained at two separate major financial institutions in the United States that are provided with up to \$500,000 in protection by the Securities Investor Protection Corporation ("SIPC") should such a firm close due to bankruptcy or other financial difficulties and customer assets are missing.

As of October 31, 2009 and July 31, 2009, we had no short-term investments.

We have not experienced any losses in our cash, cash equivalents and short-term investments and believe we are not exposed to any significant credit risk. At times, deposits held may exceed the amount of insurance provided by the FDIC or SIPC. Generally, these deposits may be redeemed upon demand and, therefore, are believed to bear low risk.

Other financial instruments that potentially subject us to concentrations of credit risk consist of accounts receivable. We extend credit to our customers based on credit evaluations and past payment performance, but do not obtain collateral to secure our accounts receivable.

## Revenue Recognition

During the periods presented herein our product revenue was derived from the sale of silver dihydrogen citrate ("SDC") concentrate and the sale of finished packaged products containing SDC. We recognize revenue from sales of these products under the provisions of the applicable authoritative guidance governing revenue recognition, which is generally when we ship the products free on board from either our facility or from third party packagers, we have transferred title to the goods, and we have eliminated our risk of loss.

#### Cost of Goods Sold

Cost of goods sold for product sales includes direct and indirect costs to manufacture products, including materials consumed, manufacturing overheads, shipping costs, salaries, benefits and related expenses of operations.

## Intangible Assets / Long-Lived Assets

Our intangible assets primarily consist of the worldwide patent portfolio of our silver ion technologies. Outside legal costs and filing fees related to obtaining patents are capitalized as incurred. The total amounts capitalized for pending patents were \$58,900 and \$19,700 in the three month periods ended October 31, 2009 and 2008, respectively. Patents are stated net of accumulated amortization of \$1,296,500 and \$1,252,200 at October 31, 2009 and July 31, 2009, respectively. The cumulative cost of acquiring patents is amortized on a straight-line basis over the estimated remaining useful lives of the patents, generally between 17 and 20 years from the date of issuance. At October 31, 2009, the weighted average remaining amortization period for all patents was approximately 10.9 years. Amortization expense for the three month periods ended October 31, 2009 and 2008 was \$44,300 and \$42,600, respectively.

## Accounting for Stock-Based Compensation

We utilize the fair value method of accounting for stock-based compensation arrangements. Accordingly, the compensation cost of share-based awards exchanged for employee and director services is measured at the grant date based on the estimated fair value of the award, and is recognized as expense over the applicable service period. We do not have, and have not had during the three month periods ended October 31, 2009 or 2008, any stock option awards with market or performance conditions.

## Stock Options to Non-Employees

Charges for stock options granted to non-employees have been determined using the estimated fair value of the stock options issued, based on the Black-Scholes Option Pricing Model. During the First Quarter we recorded \$10,500 in selling expense, \$2,800 in general and administrative expense, and \$4,100 in research and development expense; and during the three month period ended October 31, 2008 we recorded \$5,000 in research and development expense, in each case for stock options granted to non-employees.

#### Cash, Cash Equivalents, Short-term Investments and Liquidity

We consider all liquid investments with maturities of ninety days or less when purchased to be cash equivalents. Our short-term investments have maturities of greater than ninety days from the date of purchase. We classify securities as "available for sale" in accordance with authoritative guidance, and carry these investments at fair value with any unrealized gains and losses reported as a component of shareholders' equity on the consolidated balance sheets and in the statements of shareholders' equity. At October 31, 2009 and July 31, 2009 we had no short-term investments.

On May 28, 2009, we closed a registered direct offering whereby we sold \$3 million of our common stock and warrants to institutional investors. Subsequently, on September 3, 2009, we closed a registered direct offering whereby we sold an additional \$3 million of our common stock and warrants to institutional investors. After fees and expenses, the aggregate net proceeds of the two offerings to us were approximately \$5.55 million.

We believe that our cash resources are sufficient to meet our anticipated needs during the next twelve months based on our assessment of historical working capital needs, operating loss trends, and our current business outlook. However, our existing cash resources may not be sufficient to fund our planned activities, and we expect that we may need additional financing in the future, through the issuance of debt, equity, convertible securities or through other means, any one of which could reduce the value to us, perhaps substantially, of our technology and its commercial potential. Such financing, if any, could also lead to the dilution of our existing shareholders. There can be no assurance that if additional financing is necessary it will be available, or if available, that such financing can be obtained on satisfactory terms. Insufficient funds could cause us to fail to execute our business plan, fail to take advantage of future opportunities, or fail to respond to competitive pressures or unanticipated customer requirements, and further may require us to delay, scale back or eliminate some or all of our research and product development programs, license to third parties the right to commercialize products or technologies that we would otherwise commercialize ourselves, or to reduce or cease operations. If adequate funds are not available when needed, we may be required to significantly modify our business model to reduce spending to a sustainable level. Such modification of our business model could also result in an impairment of assets which cannot be determined at this time.

#### Comprehensive Income

We display comprehensive income or loss and its components as part of our consolidated financial statements. Our comprehensive loss includes our net loss and certain changes in equity that are excluded from our net loss, including unrealized holding gains and losses on available for sale securities. Such changes in shareholders' equity are included in accumulated other comprehensive income or loss. For the three month periods ended October 31, 2009 and 2008, our comprehensive loss was \$1,712,000 and \$1,619,800, respectively. During the First Quarter, we did not record unrealized gains on available for sale securities; whereas during the three month period ended October 31, 2008, we recorded unrealized gains on available for sale securities of \$4,100. For the three month period ended October 31, 2009, we did not record any realized gains on the sale of available for sale securities. Realized gains on the sale of available for sale securities for the three month period ended October 31, 2008, which are included in our net loss for the period, were \$35,700.

#### Net Loss Per Common Share

We compute basic loss per share by dividing the applicable net loss by the weighted average number of common shares outstanding during the respective period. Diluted per share amounts assume the conversion, exercise or issuance of all potential common stock equivalents, including stock options and warrants, unless the effect is to reduce a loss or increase the income per common share from continuing operations. As we incurred losses in the three month periods ended October 31, 2009 and 2008, we did not include common stock equivalent shares in the computation of net loss per share as the effect would have been anti-dilutive. Therefore, both the basic and diluted loss per common share for the three month periods ended October 31, 2009 and 2008 are based on the weighted average number of shares of our common stock outstanding during the periods.

## **Recent Accounting Pronouncements**

In February 2008, the Financial Accounting Standards Board ("FASB") issued authoritative guidance providing a one year deferral of the effective date of fair market value measurement for non-financial assets and non-financial liabilities. Effective August 1, 2009, the Company implemented the guidance for non-financial assets and liabilities that are remeasured at fair value on a non-recurring basis. The adoption of this guidance did not have a material impact on our financial position or results of operations. The Company continues to evaluate the impact of the guidance, if any, on our consolidated financial statements for future periods.

In December 2007, the FASB issued authoritative guidance to establish accounting and reporting standards for the non-controlling interest in a subsidiary and for the deconsolidation of a subsidiary. It also clarifies that a non-controlling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. It also changes the way the consolidated income statement is presented, requires additional disclosures, and requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. The guidance became effective for us as of August 1, 2009; however, it did not have a material impact on our consolidated financial statements.

In April 2008, the FASB issued authoritative guidance amending the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset. The intent of the position is to improve the consistency between previously existing standards. The guidance became effective for us as of August 1, 2009; however, it did not have a material impact on our consolidated financial statements.

In June 2008, the FASB ratified authoritative guidance providing a framework for determining whether an equity-linked financial instrument (or embedded feature) is indexed to an entity's own stock, including evaluating the instrument's contingent exercise and settlement provisions, in order to determine whether the instrument should be classified as an equity instrument or a derivative instrument. The guidance became effective for us as of August 1, 2009. We have performed an evaluation of our equity-linked financial instruments that are subject to the guidance, including outstanding common stock warrants, and determined that they should be classified as equity within the consolidated balance sheets. The guidance did not have a material impact on our consolidated financial statements.

In June 2009, the FASB issued authoritative guidance for the consolidation of variable interest entities, to require an issuer to perform an analysis to determine whether the issuer's variable interest or interests give it a controlling financial interest in a variable interest entity, if any. This analysis identifies the primary beneficiary of a variable interest entity as one with the power to direct the activities of a variable interest entity that most significantly impact the entity's economic performance and the obligation to absorb losses of the entity that could potentially be significant to the variable interest. The guidance will be effective as of the beginning of the annual reporting period commencing after November 15, 2009 (our fiscal year ending July 31, 2011). We will assess the potential impact, if any, of the adoption of the guidance on our consolidated financial statements when this guidance becomes effective for us.

In June 2009, the FASB issued accounting guidance which establishes the FASB Accounting Standards Codification (the "Codification") as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with GAAP. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. The Codification superseded all existing non-SEC accounting and reporting standards. All other non-grandfathered, non-SEC accounting literature not included in the Codification is non-authoritative. This guidance became effective for us as of our fiscal quarter ended October 31, 2009. The Codification does not change GAAP and did not impact our financial position or results of operations.

In August 2009, the FASB issued new authoritative guidance for the fair value measurement of liabilities when a quoted price in an active market is not available. The new guidance is effective for reporting periods beginning after August 28, 2009 (our fiscal quarter ending January 31, 2010). We do not currently expect the implementation of this guidance to have a material impact on our consolidated financial statements.

In September 2009, the FASB issued authoritative guidance that provides additional guidance on using the net asset value per share, provided by an investee, when estimating the fair value of an alternate investment that does not have a readily determinable fair value, and enhances the disclosures concerning these investments. Examples of alternate investments that fall within the scope of this standard include investments in hedge funds and private equity, real estate, and venture capital partnerships. This guidance is effective for interim and annual periods ending after December 15, 2009 (our fiscal quarter ending January 31, 2010). We do not currently have any investments that fall within the scope of this new guidance, and we do not currently expect it to have a material impact on our consolidated financial statements or related disclosures.

In October 2009, the FASB issued authoritative guidance that amends existing revenue recognition accounting pronouncements related to multiple-deliverable revenue arrangements. The new guidance provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and how the consideration should be allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. The new guidance is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 (our fiscal year ending July 31, 2011). We do not currently expect the implementation of this guidance to have a material impact on our consolidated financial statements.

#### Note 3. Accounts Receivable

Trade accounts receivable are recorded net of allowances for doubtful accounts. Estimates for allowances for doubtful accounts are determined based on payment history and individual customer circumstances. The allowance for doubtful accounts was zero at October 31, 2009 and July 31, 2009, respectively.

During the fiscal year ended July 31, 2008 ("Fiscal 2008"), we granted non-exclusive distribution and blending rights to a new distributor for the sale of SDC-based products in Colombia. In addition, we granted non-exclusive distribution and blending rights to a second distributor, which is affiliated with the first distributor, for the sale of SDC-based products in Argentina, Venezuela, Panama and Costa Rica. The invoiced total for both distributors was \$781,600. The \$781,600 receivable included \$57,000 for amounts billed at cost to the distributors in August 2008 for parts shipped directly to them by one of our U.S. packaging suppliers. Subsequent to this transaction, we have not sold any products to either of the two referenced distributors.

During the three month period ended January 31, 2009, we determined these accounts to be delinquent, established a full reserve and recorded \$781,600 as bad debt expense, within general and administrative expense. The referenced amounts remain uncollected, and we have written off the full receivable of \$781,600.

Management currently considers all other accounts receivable to be fully collectible.

#### Note 4. Sales of Common Stock

On September 3, 2009 we closed a registered direct offering whereby we sold \$3 million of our common stock and warrants to institutional investors. A shelf registration statement relating to the securities sold in the offering was declared effective by the SEC on May 8, 2009. Under the terms of the offering, we issued to the investors 1,818,182 shares of our common stock, and warrants to purchase 727,272 shares of our common stock. The common stock was sold at a price of \$1.65 per share, and the investors received warrants to purchase 0.4 shares of our common stock at an exercise price of \$2.10 per share for each share of common stock they purchased in the offering. The fair value of the investor warrants, based on their fair value relative to the common stock issued, was \$1,270,100 (based on the Black-Scholes Option Pricing Model assuming no dividend yield, volatility of 159.59%, and a risk-free interest rate of 2.39%). The warrants will be exercisable as of March 3, 2010, and will expire five years from that date. In addition we paid a fee of \$180,000 to Rodman & Renshaw, LLC ("Rodman") in consideration for its services as the placement agent in the offering. We also issued to Rodman and its principals, warrants to purchase 90,909 shares of our common stock at an exercise price of \$2.0625 per share. The fair value of the warrants issued to Rodman, based on their fair value relative to the common stock issued, was \$154,900 (based on the Black-Scholes Option Pricing Model assuming no dividend yield, volatility of 159.59%, and a risk-free interest rate of 2.39%). These warrants will be exercisable as of March 3, 2010, and will expire on May 7, 2014.

After fees and expenses, the net proceeds of the offering to us were \$2,783,233, which will be used for working capital.

Note 5. Other Equity and Common Stock Transactions

We paid no cash dividends during any of the periods presented, and have never paid cash dividends.

In August 2009, we entered into a one year agreement with two independent third party consultants who joined our Advisory Panel. Each consultant was granted an option to purchase 25,000 shares of common stock, with a two year term and vesting in bi-annual increments over one year. The options, which have exercise prices of \$1.85 and \$1.79, were valued at \$16,600 (based on the Black-Scholes Option Pricing Model, assuming no dividend yield, volatility of 99.87% and a risk free interest rate of 0.43%) and \$14,800 (based on the Black-Scholes Option Pricing Model, assuming no dividend yield, volatility of 99.92% and a risk free interest rate of 0.42%), respectively. The options will be revalued quarterly until fully vested, with any change in fair value expensed.

No stock options or warrants were exercised during the First Quarter.

On October 12, 2009, the Company entered into an amended and restated employment agreement with Michael L. Krall, our Chief Executive Officer, which agreement amends and restates in its entirety the employment agreement the Company previously entered into with Mr. Krall effective as of April 17, 1996. In addition, on October 12, 2009, the Company entered into employment agreements with Andrew Buckland, our Chief Financial Officer, and Donna Singer, our Executive Vice President. The three agreements are collectively referred to as "the Agreements". Included in the Agreements is a provision for the executive to have a period of not less than one hundred twenty (120) days to exercise their then outstanding stock options following any termination of the executive's employment for any reason other than for Cause (as defined in the Agreements). Such period (the "Washout Period") can in no event be beyond the maximum permitted expiration date. Prior to the Agreements, the Washout Period defined in the stock option agreements for the outstanding options held by each of the executives ranged from three (3) days to 90 days. We determined the fair value of the change in the terms of the options to be the difference in the estimated fair value immediately before and immediately after the date of the Agreements, using the Black-Scholes Option Pricing Model. We recorded a change in fair value of \$29,000 related to vested options as an expense within the consolidated statement of operations for the First quarter. A change in fair value of \$5,500 related to unvested options will be amortized over the remaining vesting periods.

During the First Quarter we also recorded \$221,700 of expense for stock and options issued to employees, officers and directors in prior periods.

At October 31, 2009, we had outstanding warrants to purchase 2,229,906 shares of our common stock with exercise prices ranging from \$2.06 to \$8.60. These warrants expire at various times between March 2011 and March 2015. In June 2008, the FASB ratified authoritative guidance, which became effective for us as of August 1, 2009, providing a framework for determining whether an equity-linked financial instrument (or embedded feature) is indexed to an entity's own stock, including evaluating the instrument's contingent exercise and settlement provisions, in order to determine whether the instrument should be classified as an equity instrument or a derivative instrument. We performed an evaluation, at August 1, 2009 and October 31, 2009, of our equity-linked financial instruments subject to the guidance, including outstanding common stock warrants, and determined that they should be classified as equity within the consolidated balance sheets.

#### Note 6. Stock-Based Compensation

We have, or have had during the fiscal years presented herein, the following equity incentive plans (the "Plans") pursuant to which we have granted options to acquire our common stock: the 1998 Directors and Officers Stock Option Plan; the 2001 Directors and Officers Stock Option Plan: the 2001 ETIH2O Stock Option Plan; the 2001 Consultants and Advisors Stock Option Plan; the 2002 Non-Qualified Stock Option Plan; the 2002 Employee Incentive Stock Option Plan; the 2004 Consultants and Advisors Stock Option Plan; and the 2007 Equity Incentive Plan. The Plans are administered by the Compensation Committee of the Board of Directors (the "Compensation Committee"). The exercise price for stock options, or the value of other incentive grants granted under the Plans, are set by the Compensation Committee but may not be for less than the fair market value of the shares on the date the award is granted. The period in which options can be exercised is set by the Compensation Committee but is not to exceed five years from the date of grant.

We recognize compensation expense for stock option awards on a straight-line basis over the applicable service period of the award. The service period is generally the vesting period, with the exception of options granted subject to a consulting agreement, whereby the option vesting period and the service period are defined pursuant to the terms of the consulting agreement. Share-based compensation expense for awards granted subsequent to July 31, 2006 is based on the grant date fair value estimated using the Black-Scholes Option Pricing Model. The following methodology and assumptions were used to calculate share based compensation for the three month periods ended October 31, 2009 and 2008:

For the three month periods ended October 31,

	2009	2008		
			97.70% -	
Expected price volatility	99.87% - 99.92	2%	103.18	%
Risk-free interest rate	0.42% - 0.43	%	2.0	%
Expected rate of forfeiture	0.0	%	0.0	%
Expected dividend yield	0.0	%	0.0	%
Weighted average expected term	1.0 years		1.89 year	rs

Expected price volatility is the measure by which our stock price is expected to fluctuate during the expected term of an option. Expected volatility is derived from the historical daily change in the market price of our common stock, as we believe that historical volatility is the best indicator of future volatility. For stock options granted subsequent to July 31, 2006, we have excluded the period prior to November 1, 2005 from our historical price volatility, as during this period our market price reflected significant uncertainty associated with both our arbitration proceedings against Falken Industries and our ability to close the sale of the assets of the Water Treatment Division. We believe that the volatility of the market price of our common stock during periods prior to November 1, 2005 is not reflective of future expected volatility.

Following the guidance of Staff Accounting Bulletin No. 107 ("SAB 107"), we have been following the "Simplified Method" to determine the expected term of "Plain Vanilla" options issued to employees and directors. All of our outstanding options granted to employees and directors are Plain Vanilla options. Under the Simplified Method, the expected term is presumed to be the mid-point between the vesting date and the end of the contractual term. In SAB 107, the Staff stated that it would not expect a company to use the Simplified Method for share option grants after December 31, 2007, however on December 21, 2007 the SEC published Staff Accounting Bulletin No. 110 ("SAB 110"), which expressed the views of the Staff regarding the continued use of the Simplified Method in certain circumstances where a company is unable to rely on historical data. We are unable to rely on our historical exercise data as there have been only a limited number of option exercises in recent periods; there have been a limited number of plan participants which is expected to grow; our common stock was traded until April 2008 on the illiquid Bulletin Board but our common stock is now listed on the NASDAO Capital Market; we have had over recent years significant trading blackout periods for employees and directors; there has been minimal employee and director turnover; we have recently changed the terms of employee stock option grants to reduce the term of such grants; there are no comparable companies in terms of size, location and industry (particularly as we are developing a platform technology and operate in multiple industries); and we have had significant structural changes in our business including the sale of the Water Treatment Division and abandonment of our Triglycylboride technology, and expect to continue to change in the foreseeable future. We are therefore, under the guidance of SAB 110, continuing to use the Simplified Method to determine the expected term of options issued to employees and directors, but will continually evaluate our historical data as a basis for determining the expected terms of such options.

Our estimation of the expected term for stock options granted to parties other than employees or directors is the contractual term of the option award. For the purposes of estimating the fair value of stock option awards, the risk-free interest rate used in the Black-Scholes calculation is based on the prevailing U.S. Treasury yield as determined by the U.S. Federal Reserve. We have never paid any cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future.

Stock-based compensation expense recognized in the consolidated statements of operations is based on awards ultimately expected to vest, reduced for estimated forfeitures. Authoritative guidance requires forfeitures to be estimated at the time of grant, and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Historically, we have not had significant forfeitures of stock options granted to employees and directors. A significant number of our historical stock option grants were fully vested at issuance or were issued with short vesting provisions. Therefore, we have estimated the forfeiture rate of our outstanding stock options as zero, but will continually evaluate our historical data as a basis for determining expected forfeitures.

The following table sets forth the share-based compensation expense recorded in our consolidated statements of operations for the three month periods ended October 31, 2009 and 2008 resulting from share-based compensation awarded to our employees, directors and third party service providers:

	Three Months Ended October 31, 2009	Three Months Ended October 31, 2008
Share-based compensation for employees and directors:	φ10.coo	Ф
Selling expense	\$19,600	\$-
General and administrative expenses	195,600	57,400
Research and development	24,800	-
Total share-based compensation for employees and directors	240,000	57,400
Share-based compensation for third party service providers:		
Selling expense	\$10,500	\$-
General and administrative expenses	2,800	24,600
Research and development	4,100	5,000
Total share-based compensation for third party service providers	17,400	29,600
Total share-based compensation expense	\$257,400	\$87,000

A summary of stock option activity is as follows:

	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value (\$000's)
Balance at July 31, 2009	6,175,216	\$1.80	\$3,836
Granted	50,000	\$1.82	
Exercised	-	-	
Forfeited / Cancelled	(113,300	) \$1.99	
Balance at October 31, 2009	6,111,916	\$1.79	\$3,388

		Outstanding			Exercisable	
		Weighted Average Remaining	Weighted		Weighted Average Remaining	Weighted
Range of	Number of	Contractual	Average	Number of	Contractual	Average
Exercise	Shares	Life (in	Exercise	Shares	Life	Exercise
Prices	Outstanding	years)	Price	Exercisable	(in years)	Price
\$0.50 to						
\$0.75	1,560,000	0.52	\$0.53	1,560,000	0.52	\$0.53
\$0.80 to \$1.20	711,666	1.12	\$0.81	711,666	1.12	\$0.81
\$1.50 to \$7.50	3,840,250	2.29	\$2.49	2,911,250	1.79	\$2.51
	6,111,916	1.70	\$1.79	5,182,916	1.32	\$1.68

Cash received from options and warrants exercised for the three month periods ended October 31, 2009 and 2008 was zero and \$165,100, respectively. The intrinsic value of all stock options exercised during the three month periods ended October 31, 2009 and 2008 was zero and \$505,800, respectively, and the weighted-average grant date fair value of stock options granted during the three month periods ended October 31, 2009 and 2008 was \$0.63 and \$2.30, respectively.

As of October 31, 2009, there was \$1,341,700 of unrecognized non-cash compensation cost related to unvested options, which will be recognized over a weighted average period of 3.0 years.

A summary of restricted stock activity is as follows:

	Number of
	Shares
Unvested at July 31, 2008	86,800
Granted	-
Exercised	-
Forfeited / Cancelled	(21,700)
Unvested at October 31, 2009	65,100

During the three month periods ended October 31, 2009 and 2008, we recognized stock based compensation expense for restricted stock of \$27,500 and zero respectively. As of October 31, 2009, there was \$82,500 of unrecognized

non-cash compensation cost related to unvested restricted shares, which will be recognized over a weighted average period 0.5 years.

## Note 7. Inventory

Inventories are stated at the lower of cost or net realizable value using the average cost method. Inventories at October 31, 2009 and July 31, 2009 consisted of:

	October 31,			
	2009		July 31, 2009	
Raw Materials	\$	210,800	\$	194,700
Work in Progress		-		-
Finished Goods		219,200		227,000
	\$	430,000	\$	421,700

Included in our inventory of finished goods as of October 31 and July 31, 2009 are approximately 12,000 gallons of SDC concentrate that we purchased from an unrelated third party in a lien sale for \$27,467. This transaction had no material impact on our consolidated statements of operations for the First Quarter, however it is expected to temporarily reduce our cost of goods sold per gallon of SDC concentrate sold in future periods.

## Note 8. Business Segment and Sales Concentrations

Operating segments are defined as components of an enterprise for which separate financial information is available and evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. We believe that based upon the end use of our products, the value added contributions made by us, the regulatory requirements, our customers and partners, and the strategy required to successfully market finished products, we are operating in a single segment.

To date, our customers have been strategic partners who develop markets for, and distributors who sell, products containing our SDC technology. During the First Quarter, 92% of sales were made to two such customers. 34% of revenue for the First Quarter was derived from sales made to U.S. domestic customers, and 66% was derived from sales made to international customers. In some cases we have, or may have in future periods, distributors or strategic partners to whom we have granted rights to sell our technology in multiple countries. Generally, we do not require such distributors to report to us the quantities of products that they sell in each country. In such cases, we report revenues based on the country to which we ship products.

During the First Quarter, 98% of our sales were of bulk Axen30 or finished packaged products containing Axen 30, our ready to use product, and 2% of our sales were of bulk SDC concentrate. During the same period of the prior year, 92% of our sales were of bulk Axen30 or finished packaged products containing Axen 30, and 8% of our sales were of bulk SDC concentrate.

All of our tangible assets are located in the United States.

## Note 9. Subsequent Events

Our management has evaluated events as of December 9, 2009, which is the last practical date prior to the filing of this Quarterly Report. All events to this date are recognized or disclosed in the financial statements herein, to the extent that they impact our balance sheets as at October 31, 2009 or July 31, 2009; or our statements of operations, or statements of cash flows for the three month periods ended October 31, 2009 or 2008. Other events that occurred subsequent to October 31, 2009 include the following:

In November, we received \$85,000 from the exercise of stock options on 170,000 shares at an exercise price of \$0.50 per share. In addition, in the same month there was a net exercise of 50,000 stock options with an exercise price of \$0.50, which resulted in the issuance of 37,140 shares of our common stock to the optionee. As these options were net exercised, we did not receive any cash.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This report contains forward-looking statements. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential" or "continue," the negative of such terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither we, nor any other person, assume responsibility for the accuracy and completeness of the forward-looking statements. We are under no obligation to update any of the forward-looking statements after the filing of this Quarterly Report on Form 10-Q to conform such statements to actual results or to changes in our expectations.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes and other financial information appearing elsewhere in this Quarterly Report. Readers are also urged to carefully review and consider the various disclosures made by us which attempt to advise interested parties of the factors which affect our business, including without limitation the disclosures made in Item 1A of Part II of this Quarterly Report under the Caption "Risk Factors" and in our audited consolidated financial statements and related notes included in our Annual Report on Form 10-K for the fiscal year ended July 31, 2009 ("Fiscal 2009"), previously filed with the Securities and Exchange Commission ("SEC").

Risk factors that could cause actual results to differ from those contained in the forward-looking statements include but are not limited to: our limited operating history; our history of losses; our future capital needs; the rapidly changing technologies and market demands; the failure of our products to achieve broad acceptance; our failure to successfully compete; our dependence on a single product; our failure to comply with government regulation; the loss of a key member of our management team; our failure to protect our intellectual property; our exposure to intellectual property and product liability claims; changes in government policies and other risks identified in Part II, Item 1A of this Quarterly Report on Form 10-Q.

The financial statements presented herein, and discussed below, have been prepared in accordance with U.S. Generally Accepted Accounting Principles.

#### Overview

PURE Bioscience (sometimes referred to herein as the "Company," "we" "us" or "our") was incorporated in the state o California on August 24, 1992. We began as a provider of pharmaceutical water purification products for the pharmacy market. In 2000, we commenced investments in the development of novel bioscience technologies, and subsequent to the May 2005 sale of our Water Treatment Division we have been exclusively focused on the development and commercialization of our current and future bioscience products.

We are expanding into markets with broad potential by developing new, proprietary bioscience products based upon our patented silver ion antimicrobial technologies. We are developing technology-based bioscience products, including our silver dihydrogen citrate-based antimicrobials, which we believe can provide novel, non-toxic solutions to numerous global health challenges and represent innovative advances in diverse markets. We believe that our technologies are in a position to contribute significantly to today's global trend toward industrial and consumer use of environmentally friendly products, while providing competitive advantages in efficacy and safety.

## Bioscience Technologies

Our flagship bioscience technology is a patented, aqueous antimicrobial called silver dihydrogen citrate ("SDC"). A new molecular entity, SDC is an electrolytically generated source of stabilized ionic silver that can serve as the basis for a broad range of products in diverse markets. SDC liquid is colorless, odorless, tasteless, non-caustic and formulates well with other compounds. As a platform technology, our SDC-based antimicrobial is distinguished from competitors

in the marketplace because of its superior efficacy combined with reduced toxicity. We are producing pre-formulated, ready-to-use products for private label distribution, as well as varying strengths of SDC concentrate as an additive or raw material for inclusion in other companies' products, including as an active pharmaceutical ingredient. In addition to SDC, we have obtained patent protection for ionic silver-based molecular entities utilizing 14 organic acids other than citric acid.

We also own certain rights to a patent-pending pesticide technology, Triglycylboride which, like SDC, provides effective results without human toxicity and is an alternative to traditional poisons. Triglycylboride has been formulated into the products RoachX and AntX, however these products are not currently being actively marketed or developed.

#### Sources of Revenue

Our principal sources of revenue are comprised of sales of SDC concentrate as well as both bulk and individually bottled SDC-based hard surface disinfectant. SDC concentrate is sold to distributors that either resell the concentrate as an active ingredient or preservative in other companies' products, or blend the product into hard surface disinfectant products for sale to retail, commercial and institutional customers. SDC-based hard surface disinfectant has historically been sold in bulk and as individually bottled products to distributors that in turn sell the product to retail, commercial and institutional customers.

In October 2009, we announced that we had expanded our business strategy through an alliance with a Dallas-based sales and marketing organization, Richmont Sciences, LLC ("Richmont"). Richmont will provide us with sales, marketing and branding services that will enable us to sell SDC-based antibacterial, antiviral and antifungal hard surface disinfectants directly to global retail, commercial and institutional customers, subsequent to regulatory approval. Richmont will also market, after regulatory approvals are obtained, our sanitizer for surfaces touched by food in restaurants, hotels, food processing plants, and other environments. In addition, Richmont will sell SDC concentrate as an active ingredient and as a preservative. Under our agreement with Richmont, we expect to be able to sell products to larger and more established customers than we have historically been able to sell our products to. We expect to recognize the revenues for products sold under the agreement and to pay marketing fees to Richmont based upon those revenues.

We will also continue to sell products through our existing distributors. We have entered into distribution agreements with multiple distributors in the United States to market our EPA-approved Axen 30 hard surface disinfectant under their own labels, and a number of such products have recently been launched, or are expected to be launched in future periods. We also have a strategic agreement with BASF, whereby we have granted BASF the right to resell our SDC concentrate within the global personal care, household and institutional markets.

Our revenues have historically fluctuated from period to period. For example, in Fiscal 2009 we reported revenues from product sales of \$478,000, compared with revenue from product sales for our fiscal year ended July 31, 2008 ("Fiscal 2008"), of \$1,487,000. Among other factors, during Fiscal 2008 we recorded product revenue of \$997,000 for sales to two international distributors for whom we did not recognize any revenue in Fiscal 2009.

In future periods, we expect our revenues to continue to fluctuate. In some cases, such as under our agreement with BASF, we will not be aware of the launch of products containing SDC until they are available to end-users. In February 2009 the first name brand personal care products containing SDC as the active ingredient were launched in Europe by a customer of BASF. Notwithstanding that we sold the SDC used as an active ingredient in the product, we were not able to anticipate this launch due to the contractual rights of BASF and its customer.

## Cost of Revenues and Operating Expenses

Costs of Revenue. Costs of product revenue include materials consumed, manufacturing overheads, shipping costs, salaries, benefits and related expenses of operations. In addition, included in our inventory of finished goods as of October 31, 2009 are approximately 12,000 gallons of SDC concentrate that we purchased from an unrelated third party in a lien sale. This transaction had no material impact on our consolidated statements of operations for the three month period ended October 31, 2009 (the "First Quarter"), however it is expected to temporarily reduce our cost of goods sold per gallon of SDC concentrate sold in future periods.

Gross profit on product sales represents net revenue less the costs of revenue. Gross profit percentage is highly dependent on pricing, contractual agreements, overhead allocations and other factors. We do not believe that historical gross profit margins on product sales are a reliable indicator of future gross profit margins.

Selling and Marketing. Selling and marketing expenses consist primarily of salaries and benefits, and amounts paid to third party providers for marketing, sales, public relations and advertising, along with promotional and trade show costs and travel expenses. Sales and marketing expenses also include share-based compensation allocable to employees and third party advisors performing services related to sales and marketing.

General and Administrative. General and administrative expenses include employee salaries and benefits, and amounts paid to third party providers for finance and accounting, legal activities, human resources, insurance, information technology, and other administrative activities. General and administrative expenses also include share-based compensation allocable to employees and third party advisors performing general and administrative services.

Research and Development. Research and development costs include in-house research costs, expenditures for third party testing, patent amortization, outside legal costs for maintaining issued patents, and product registration expenditures. We do not currently expect our research and development expense to grow significantly in future periods, however if opportunities arise, particularly in the development and testing of new formulations, we will evaluate the need for additional research expenditures based on potential market sizes and our estimation of the likelihood of our technology achieving successful results. Research and development expenses also include share-based compensation allocable to employees and third party advisors performing services related to research and development.

**Critical Accounting Policies** 

Accounting for Long-Lived Assets / Intangible Assets

We assess the impairment of long-lived assets, consisting of property, plant, equipment and finite-lived intangible assets, whenever events or circumstances indicate that the carrying value may not be recoverable. Examples of such events or circumstances include:

- An asset's ability to continue to generate income from operations and positive cash flow in future periods;
  - Loss of legal ownership or title to an asset;
  - Significant changes in our strategic business objectives and utilization of the asset(s); and
    - The impact of significant negative industry or economic trends.

Recoverability of assets to be held and used in operations is measured by a comparison of the carrying amount of an asset to the future net cash flows expected to be generated by the assets. The factors used to evaluate the future net cash flows, while reasonable, requires a high degree of judgment and the results could vary if the actual results are materially different than the forecasts. In addition, we base useful lives and amortization or depreciation expense on our subjective estimate of the period that the assets will generate revenue or otherwise be used by us. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less selling costs.

We also periodically review the lives assigned to our intangible assets to ensure that our initial estimates do not exceed any revised estimated periods from which we expect to realize cash flows from the technologies. If a change were to occur in any of the above-mentioned factors or estimates, the likelihood of a material change in our reported results would increase.

## Accounting for Stock-Based Compensation

Stock-based compensation expense for all stock-based compensation awards granted after August 1, 2006 is based on the grant date fair value estimated in accordance with the provisions of applicable authoritative guidance. Specifically, we estimate the weighted-average fair value of options granted using the Black-Scholes Option Pricing Model based on evaluation assumptions regarding expected volatility, dividend yield, risk-free interest rates, the expected term of the option and the expected forfeiture rate. Each of these assumptions, while reasonable, requires a certain degree of judgment and the fair value estimates could vary if the actual results are materially different than those initially applied. Prior to August 1, 2006, we were not required to record compensation cost in the consolidated financial statements for stock options issued to employees or directors.

Results of Operations for the Three Months Ended October 31, 2009 vs. Three Months Ended October 31, 2008

### Revenue and Gross Margin

For the First Quarter, product revenues of \$221,900 increased by \$111,300, or 101%, compared with the three months ended October 31, 2008. The increase is primarily due to new customers who commenced marketing activities in overseas markets in the First Quarter. Revenue for each of the quarters presented was derived primarily from sales of finished products and bulk Axen 30. To date, our customers have been strategic partners who develop markets for, and distributors who sell, products containing our SDC technology. 92% of sales for the First Quarter were made to two customers. 34% of sales for the First Quarter were made to U.S. domestic customers, compared with 98% in the same period of the prior year. In the First Quarter, 66% of revenue was derived from shipments to Taiwan, for further distribution and sale by our distributor to several Asian countries.

Gross profit for the First Quarter was \$141,700, compared with \$50,800 in the same period of the prior fiscal year. The gross margin percentage improved from 46% in the comparable period in the prior fiscal year to 65% in the First Quarter. The improvement is primarily due to an increased proportion of bulk Axen 30 sold in the First Quarter, compared with a higher proportion of finished packaged products in the comparable period in the prior year. In the First Quarter, 65% of sales were of bulk Axen 30, and 32% of sales were of finished packaged products. During the same period of the prior year, 85% of sales were of finished packaged products, which we generally sell at lower margins than our bulk products.

#### **Operating Costs**

Operating costs increased by \$161,800, or 10%, from \$1,700,600 in the three month period ended October 31, 2008, to \$1,862,400 in the First Quarter. Within these aggregate operating costs, selling expense increased \$68,700 in the First Quarter compared with the same period in the prior fiscal year. The increase in selling expense is primarily due to increases in stock option expense and in public relations expense.

General and administrative expense declined by \$77,800, or 9%, from \$1,262,400 in the three month period ended October 31, 2008, to \$1,184,600 in the First Quarter. The decrease in general and administrative expense is primarily due to reductions in payroll and related costs, and legal and accounting fees; which were partially offset by an increase in stock option and restricted stock grant expense. The increase in option and stock expense, of \$141,400, is primarily due to a change in practice for officer and director grants. In May 2009 we made option and restricted stock awards, to officers and directors, subject to vesting provisions. Prior practice had been for such awards to vest immediately. New awards are now expensed over the vesting period, rather than on their date of grant.

Research and development costs, including in-house costs, patent amortization, outside legal costs for maintaining approved patents, and product registration expenditures, increased by \$170,900, from \$287,000 in the three months ended October 31, 2008 to \$457,900 in the First Quarter. The increase is primarily related to investments in patent registrations, third party testing, and in higher payroll and related expense due to new hires for research and product development activities. Our research and development expense may continue to grow in future periods. If

opportunities arise, particularly in the development and testing of new formulations, we will evaluate the need for additional research expenditures based on potential market sizes and our estimation of the likelihood of our technology achieving successful results.

Our loss from operations before taxes increased by \$105,900, from a loss of \$1,605,300 for the three months ended October 31, 2008 to a loss of \$1,711,200 for the First Quarter.

#### Other Income

Other income declined by \$35,000 in the First Quarter compared to the same period of the prior fiscal year, due primarily to gains on the sale of T-bills recorded in the prior year. We had no such investments during the First Quarter.

## Net Loss

Our net loss after taxes increased by \$105,900 from a net loss of \$1,605,300 for the three months ended October 31, 2008 to a net loss of \$1,711,200 for the First Quarter.

## Liquidity and Capital Resources

From inception through the present, we have financed our operations primarily through sales of our equity securities, through lines of credit and the issuance of debentures, and in May 2005 by the sale of our Water Treatment Division. At October 31, 2009, we had cash and cash equivalents of \$5,600,300, an increase of \$1,386,500 from July 31, 2009.

On September 3, 2009, we closed a registered direct offering whereby we sold \$3 million of our common stock and warrants to institutional investors. Under the terms of the offering, we issued to the investors 1,818,182 shares of our common stock, and warrants to purchase 727,272 shares of our common stock. The common stock was sold at a price of \$1.65 per share, and the investors received warrants to purchase 0.4 shares of our common stock at an exercise price of \$2.10 per share for each share of common stock they purchased in the offering. In addition we paid a fee of \$180,000 to Rodman & Renshaw, LLC ("Rodman") in consideration for its services as the placement agent in the offering. We also issued to Rodman and its principals, warrants to purchase 90,909 shares of our common stock at an exercise price of \$2.0625 per share. After fees and expenses, the net proceeds of this offering to us were approximately \$2.78 million.

At October 31, 2009, we had no short-term investments and no long-term debt. Total current assets at October 31, 2009 were \$6,205,400, an increase of \$1,357,600 from July 31, 2009.

Cash used in operating activities for the First Quarter was \$1,300,000, compared with \$1,593,400 for the same three month period of the prior fiscal year. The decline in operating cash expenditures is primarily due to reduced general and administrative spending and the timing of the payment of accounts payable, which was partially offset by an increase in research and development spending.

Our operating cash outflows could be greater in future periods. Net cash used in operations was \$1,300,000 in the First Quarter, \$5,910,100 in the fiscal year ended July 31, Fiscal 2009, and \$4,404,600 in the fiscal year ended July 31, Fiscal 2008. Our future capital needs and our future profits, if any, are uncertain, and will depend on many factors including, among others, the acceptance of, and demand for, our products; our success and the success of our partners and distributors in selling our products; our success and the success of our partners in obtaining regulatory approvals to sell our products; the costs of further developing our existing, and developing new, products or technologies; the extent to which we invest in new technology and product development; and the costs associated with the continued operation, and any future growth, of our business. We believe that our cash resources are sufficient to meet our anticipated needs during the next twelve months based on our assessment of historical working capital needs, operating loss trends, and our current business outlook. However, our existing cash resources may not be sufficient to fund our planned activities, and we expect that we may need additional financing, through the issuance of debt, equity, convertible securities or through other means, any one of which could reduce the value to us, perhaps substantially, of our technology and its commercial potential. Such financing, if any, could also lead to the dilution of our existing shareholders. There can be no assurance that if additional financing is necessary it will be available, or if available, that such financing can be obtained on satisfactory terms. Insufficient funds could cause us to fail to execute our business plan, fail to take advantage of future opportunities, or fail to respond to competitive pressures or unanticipated customer requirements, and further may require us to delay, scale back or eliminate some or all of our research and product development programs, license to third parties the right to commercialize products or technologies that we would otherwise commercialize ourselves, or to reduce or cease operations. If adequate funds are not available when needed, we may be required to significantly modify our business model to reduce spending to a sustainable level. Such modification of the business model could also result in an impairment of assets which cannot be determined at this time.

During the First Quarter, cash used in investing activities was \$96,700, consisting of investments in patents of \$59,000 and purchases of property, plant and equipment of \$37,700. At October 31, 2009 the net value of our capitalized patents and our property, plant and equipment was \$1,959,400 and \$823,200, respectively. In the three month period ended October 31, 2008, cash provided by financing activities was \$451,700. Investments in patents of \$19,700 and purchases of property, plant and equipment of \$40,900 were offset by a net amount (cash sales less cash purchases) of \$512,300 provided by short-term investments.

During the First Quarter, cash provided by financing activities was \$2,783,200, all of which was derived from the net proceeds of our September 2009 registered direct offering. In the prior year period, cash provided by financing activities was \$165,100, all of which came from the exercise of stock options. We had no cash proceeds from exercise

of stock options and warrants in the First Quarter.

At October 31, 2009, we had total liabilities of \$592,100, an increase of \$9,600 from July 31, 2009.

Off Balance Sheet Arrangements

We do not have any off balance sheet arrangements.

## Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to interest rate risk at October 31, 2009 is related to our investment portfolio which consists largely of debt instruments and other securities of high quality corporate issuers and the U.S. government and its agencies. From time to time our investments may be exposed to market risk related to changes in interest rates. Our current investment policy is to maintain an investment portfolio consisting only of diversified institutional money market mutual funds investing in A-1 (S&P) or Prime-1 (Moody's); U.S. Treasury Securities, or United States Government obligations issued by or backed by a federal agency of the United States Government. We do not enter into investments for trading or speculative purposes, and our cash is deposited in, and invested through, highly rated financial institutions in the United States. While our available for sale securities are subject to interest rate risk and would fall in value if market interest rates increased, we estimate that the fair value of our investment portfolio would not decline by a material amount in the event of an increase in market interest rates. We therefore would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

We have operated mainly in the United States, and the majority of our sales since inception have been made in U.S. dollars. Further, all of our sales to international markets have been to independent parties in transactions conducted in U.S. dollars. Accordingly, we have not had any material exposure to foreign currency rate fluctuations.

#### Item 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, who also acts as our Principal Accounting Officer, as appropriate, to allow timely decisions regarding required disclosure based closely on the definition of "disclosure controls and procedures" in Rule 13a-14(c). In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

#### Evaluation of Disclosure Controls and Procedures

We have carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer/Principal Accounting Officer, of the effectiveness of the design and operation of all of our disclosure controls and procedures. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer/Principal Accounting Officer concluded that our disclosure controls and procedures were effective as of October 31, 2009.

## Changes in Internal Control Over Financial Reporting

We made no changes in our internal control over financial reporting during the First Quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II - OTHER INFORMATION

## Item 1. Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are not currently aware of any such legal proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

#### Item 1A. Risk Factors

Except for the historical information contained herein or incorporated by reference, this quarterly report on Form 10-Q and the information incorporated by reference contains forward-looking statements that involve risks and uncertainties. These statements include projections about our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. These statements are not guarantees of future performance or events. Our actual results may differ materially from those discussed here. Factors that could cause or contribute to differences in our actual results include those discussed in the following section, as well as those discussed in Part I, Item 2 entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this quarterly report on Form 10-Q and in any other documents incorporated by reference into this report. You should consider carefully the following risk factors, together with all of the other information included or incorporated in this quarterly report on Form 10-Q. Each of these risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock. There may be additional risks that we do not presently know of or that we currently believe are immaterial which could also impair our business and financial position. If any of the events described below were to occur, our financial condition, our ability to access capital resources, our results of operations and/or our future growth prospects could be materially and adversely affected and the market price of our common stock could decline. As a result you could lose some or all of any investment you may have made or may make in our common stock.

We have a history of losses, and we may not achieve or maintain profitability

We had a loss of \$1,656,900 after taxes for the First Quarter, a loss of \$7,067,300 after taxes for the Fiscal 2009, and a loss of \$6,540,300 after taxes for Fiscal 2008. As of October 31, 2009, we had an accumulated deficit of approximately \$40.2 million. We may continue to have losses in the future. If the penetration into the marketplace of SDC takes longer than anticipated, revenue growth is slower than anticipated or operating expenses exceed expectations, it may take an unforeseen period of time to achieve or sustain profitability and we may never achieve or sustain profitability. Slower than anticipated revenue growth could force us to reduce research, testing, development and marketing of our technology and/or force us to reduce the size and scope of our operations, or cease operations altogether.

We do not yet have significant cash inflows from product sales or from other sources of revenue to offset our ongoing and planned investments in corporate infrastructure, research and development projects, regulatory submissions, business development activities, and sales and marketing, among other investments. These investments may not be successful. In addition, some of these investments cannot be postponed and we may be contractually or legally obligated to make them. In future periods we may need to seek additional capital through the issuance of debt, equity, convertible securities or through other means, any one of which could reduce the value, perhaps substantially, of our outstanding common stock. We currently have no long-term debt, however the issuance of debt, equity, convertible securities, or other financial instruments in future periods, if any, could lead to the dilution of our existing shareholders. There is no guarantee that we would be able to obtain capital on terms acceptable to us, or at all. Insufficient funds could cause us to fail to execute our business plan, fail to take advantage of future opportunities, or fail to respond to competitive pressures or unanticipated customer requirements, and further may require us to delay, reduce or eliminate some or all of our research and product development programs, license to third

parties the right to commercialize products or technologies that we would otherwise commercialize ourselves, sell some or all of our intellectual property, or to reduce or cease operations.

The risks associated with our business may be more acute during periods of economic slowdown or recession. In addition to other consequences, these periods may be accompanied by decreased consumer spending generally, as well as decreased demand for, or additional downward pricing pressure on our products. Accordingly, any prolonged economic slowdown or a lengthy or severe recession with respect to either the U.S. or the global economy is likely to have a material adverse effect on our results of operations, financial condition and business prospects. As a result, given the recent deterioration in the U.S. and global economies, as well as the decreasing purchasing power of consumers and institutions, we expect that our business will continue to be adversely affected for so long as, and to the extent that, such adverse economic conditions exist.

If our efforts to achieve and maintain market acceptance of our core SDC technology are not successful, or we fail to obtain necessary governmental approvals, we are unlikely to attain profitability

We have invested a significant portion of our time and financial resources in the development and commercialization of our core SDC technology. We expect that sales of SDC will constitute a substantial portion, or all, of our revenues in future periods. Any material decrease in the overall level of sales or expected sales of, or the prices for, SDC, whether as a result of competition, change in customer demand, or any other factor, would have a materially adverse effect on our business, financial condition and results of operations.

We are marketing our new antimicrobial silver ion technology to industrial and consumer markets. These products have not yet been accepted into the marketplace, and may never be accepted. In addition, even if our products achieve market acceptance, we may not be able to maintain product sales or other forms of revenue over time if new products or technologies are introduced that are more favorably received than our products, are more cost-effective or otherwise render our products less attractive or obsolete. Other risks involved in introducing these new products include liability for product effectiveness and safety, and competition from existing or emerging sources. Additionally, government regulation in the U.S. and in other countries is a significant factor in the development, manufacturing and marketing of many of our products and in our ongoing research and development activities. We believe that all products derived from SDC, or products that may be derived from SDC in future periods, require or will require approval by government agencies prior to marketing or sale in the U.S. or overseas. Complying with applicable government regulations and obtaining necessary clearances or approvals can be time consuming and expensive, and there can be no assurance that regulatory review will not involve delays or other actions adversely affecting the marketing and sale of our products. For example, regulatory review of SDC by the EPA has historically been time consuming and expensive, due primarily, we believe, to the novel nature of our technology. While we cannot accurately predict the outcome of such regulatory processes, we expect the review process to remain time consuming and expensive as we, or our partners, apply for approval to market new formulations or to make additional claims. We also cannot predict the extent or impact of future legislation or regulation in the U.S. or overseas.

Some of our new bioscience applications, for example those aimed at healthcare, food preparation and agriculture markets, will also require approval by government agencies prior to marketing or sale in the U.S. or overseas. Until we, or our partners, obtain approvals from the appropriate regulatory authorities for future potential product applications, if any, we will not be able to market or sell such products, which would limit our revenues. Even after approval, if any, we will remain subject to changing governmental policies regulating antimicrobial products.

If we are not able to manage our anticipated growth effectively, we may not become profitable

We anticipate that expansion will continue to be required to address potential market opportunities for our SDC technology. There can be no assurance that our infrastructure will be sufficiently scalable to manage any future growth. There also can be no assurance that if we continue to invest in additional infrastructure, we will be effective in expanding our operations or that our systems, procedures or controls will be adequate to support such expansion. In addition, we will need to provide additional sales and support services to our partners if we achieve our anticipated growth with respect to the sale of our SDC technology for various applications. Failure to properly manage an increase in customer demands could result in a material adverse effect on customer satisfaction, our ability to meet our contractual obligations, and on our operating results.

The industries in which we operate are heavily regulated and we may be unable to compete effectively

We are a bioscience company focused on the marketing and continued development of our electrolytically generated stabilized ionic silver technology, including our flagship SDC antimicrobial. The risks, regulatory hurdles and costs of doing business in our target markets are high. Our SDC is a platform technology rather than a single use applied technology. As such, products developed from the platform fall under the jurisdiction of multiple U.S. and international regulatory agencies. We currently have U.S. EPA registration for our 2400-parts per million (ppm) technical grade SDC concentrate (trade name Axenohl), as well as for our Axen and Axen30 hard surface disinfectant products. In addition, in August 2009 we obtained EPA registration for an SDC-based sanitizer for food contact surfaces. In addition to the Federal EPA, each of the 50 United States has its own government agency that regulates pesticide sales into their state. Prior to distributing a product into any of these states, a registration from the state is required. There can be no guarantee that a particular state, or any state, will continue to allow the sale of SDC-based products, or grant any new approvals in future periods.

We intend to fund and manage additional EPA-regulated product development internally, in conjunction with our regulatory consultants and potentially by partnering with other third parties. We are also partnering, or intend to partner, with third parties who are seeking, or intend to seek, approvals to market SDC-based products in markets outside the U.S. However, the introduction of additional regulated antimicrobial products in the U.S. or in markets outside the U.S. could take several years, or may never be achieved. Existing state, federal or international approvals may not be maintained. Additionally, doing business internationally carries a great deal of risk with regard to foreign government regulation, banking, currency fluctuation, and many other factors.

## We are subject to intense competition

Our silver ion and other products compete in highly competitive markets dominated by extremely large, well financed domestically and internationally recognized chemical and pharmaceutical companies. Many of our competitors have greater financial resources than we do in the areas of sales, marketing, branding and product development, and we expect to face additional competition from these competitors in the future. Many of our competitors already have well established brands and distribution. Focused competition by chemical and pharmaceutical giants could substantially limit or eliminate our potential market share and ability to profit from our products and technologies. Our ability to compete will depend upon our ability, and the ability of our distributors and other partners, to develop brand recognition and novel distribution methods, and to displace existing, established and future products in our relevant target markets. We or our partners or distributors may not be successful in doing so.

We rely on a small number of key supply ingredients in order to manufacture our products

All of the supply ingredients used to manufacture our products are readily available from multiple suppliers. However, commodity prices for these ingredients can vary significantly and the margins that we are able to generate could decline if prices rise. For example, both silver and citric acid prices have been volatile recently. In many of our distribution and development agreements, we are unable to raise our product prices to our customers quickly to maintain our margins, and significant price increases for key inputs would therefore have an adverse effect on our results of operations.

We are subject to substantial regulation related to quality standards applicable to our manufacturing and quality processes. Our failure to comply with applicable quality standards could have an adverse effect on our business, financial condition, or results of operations

The EPA regulates the registration, manufacturing, and sales and marketing of many of our products, and those of our distributors and partners, in the United States. Significant government regulation also exists in overseas markets. Compliance with applicable regulatory requirements is subject to continual review and is monitored through periodic inspections and other review and reporting mechanisms.

Failure by us or our partners to comply with current or future governmental regulations and quality assurance guidelines could lead to temporary manufacturing shutdowns, product recalls or related field actions, product shortages or delays in product manufacturing. Efficacy or safety concerns and/or manufacturing quality issues with respect to our products or those of our partners could lead to product recalls, fines withdrawals, declining sales, and/or our failure to successfully commercialize new products or otherwise achieve revenue growth.

In addition, the FDA and comparable agencies in many foreign countries impose substantial limitations on the introduction of new products through costly and time-consuming laboratory and clinical testing and other procedures. The process of obtaining FDA and other required regulatory approvals is lengthy, expensive and uncertain. There is no guarantee that either our existing partners or any other potential partner, or we, will be able to obtain the resources necessary to further develop our technology or obtain regulatory approvals, or that the products will be successful in meeting the strict criteria imposed by the FDA. It may be several years before we, or any third party to whom we grant rights to use our silver ion technologies, are able to introduce any FDA regulated antimicrobial pharmaceutical products containing our technology.

If a natural or man-made disaster strikes our manufacturing facility, we will be unable to manufacture our products for a substantial amount of time and our sales and profitability will decline

Our sole manufacturing facility and the manufacturing equipment we use to produce our products would be costly to replace and could require substantial lead-time to repair or replace. The facility may be affected by natural or man-made disasters and in the event they were affected by a disaster, we would be forced to set up alternative production capacity, or rely on third party manufacturers to whom we would have to disclose our trade secrets. Although we possess insurance for damage to our property and the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses, may not continue to be available to us on acceptable terms, or at all, and may not address the marketing and goodwill consequences of our inability to provide products for an extended period of time.

If we are unable to successfully develop or commercialize new applications of our SDC technology, our operating results will suffer

In addition to its use on inanimate surfaces, we believe that our SDC technology also shows promise as a broad-spectrum antimicrobial for use in human and veterinary healthcare products. We plan to pursue additional EPA and FDA regulatory approvals for other applications. We have entered into agreements with FTA Therapeutics ("FTA") for the development and commercialization of certain FDA regulated SDC-based products. However, we do not exercise any control over these development partners. FTA's resources are limited and progress to date on all indications has been slow. Any products developed may never achieve regulatory approval and may never be commercialized. If they are commercialized, we may not receive a share of future revenues that provides an adequate return on our historical or future investment.

Our ability to generate increased revenue depends in part upon the ability and willingness of our current and potential strategic partners in both FDA and non-FDA environments to increase awareness of our technology to their customers, and to provide implementation services. If our strategic partners fail to increase awareness of our technology or to assist us in getting access to decision-makers, then we may need to increase our marketing expenses, change our marketing strategy or enter into marketing relationships with different parties, any of which could impair our ability to generate increased revenue or to generate profits from our technology.

Because we are an early stage company, it is difficult to evaluate our prospects; our financial results may fluctuate and these fluctuations may cause our stock price to fall

Since acquiring the rights to our SDC technology, we have encountered and likely will continue to encounter risks and difficulties associated with new and rapidly evolving markets. These risks include the following, among others:

- we may not increase our sales to our existing customers and expand our customer base;
- we may not succeed in maintaining and expanding our current sales and in penetrating other markets and applications of our SDC technology;
- we or our partners and/ distributors may not establish and maintain effective marketing programs and create product awareness or brand identity;
  - we may not attract and retain key business development, technical and management personnel;
    - we may not succeed in locating strategic partners and licensees of our technology;
      - we may not effectively manage our anticipated growth; and
      - we may not be able to adequately protect our intellectual property.

In addition, because of our limited operating history and the early stage of the market for our SDC technology, we have limited insight into trends that may emerge and affect our business. Forecasting future revenues is difficult, especially since our technology is novel and we are at the early stages of the adoption of our technology. Market acceptance of our products may change rapidly. In addition, our customer base is highly concentrated. Fluctuations in the buying patterns of our current or potential customers for any reason, could significantly affect the level of our sales on a period to period basis. As a result, our financial results could fluctuate to an extent that may not meet market expectations and that also may adversely affect our stock price. There are a number of other factors that could cause our financial results to fluctuate unexpectedly, including product sales, the mix of product sales, the cost of product sales, the achievement and timing of research and development and regulatory milestones, changes in expenses, including non-cash expenses such as the fair value of stock options granted, and manufacturing or supply issues, among other issues.

We have no product distribution experience and we expect to rely on third parties who may not successfully sell our products

We have no product distribution experience and currently rely and plan to rely primarily on product distribution arrangements and/or sales and marketing services provided by third parties. We also plan to license our technology to certain third parties for commercialization of certain applications. We expect to enter into additional distribution agreements and licensing agreements in the future, and we may not be able to enter into these additional agreements on terms that are favorable to us, if at all. In addition, we may have limited or no control over the distribution activities of these third parties. These third parties could sell competing products and/or may devote insufficient sales efforts to our products. As a result, our future revenues from sales of our products, if any, will depend on the success of the efforts of these third parties.

We expect to rely on third parties to develop SDC-based products and they may not do so successfully or diligently

We rely in part on third parties to whom we license rights to our technology to develop products containing SDC for many of the applications for which we believe SDC-based products have, or may have, market opportunities. Generally, under our contractual relationships with these third parties, we rely on the third party to fund and direct product development activities and appropriate regulatory filings. Any of these third parties may not be able to successfully develop such SDC-based products, due to, among other factors, a lack of capital; a lack of appropriate diligence; a change in the evaluation by the third party of the market potential for SDC-based products; technical failures; and poorer than expected test results resulting from trial use of any products that may be developed.

If we are unable to obtain, maintain or defend patent and other intellectual property ownership rights relating to our technology, we or our collaborators and distributors may not be able to develop and market products based on our technology, which would have a material adverse impact on our results of operations and the price of our common stock

We rely and expect in the future to rely on a combination of patent, trademark, trade secret and copyright law, and contractual restrictions to protect the proprietary aspects of our technology and business. These legal protections afford only limited protection for our intellectual property and trade secrets. Despite efforts to protect our proprietary rights, unauthorized parties may attempt to copy aspects of our proprietary technology or otherwise obtain and use information that we regard as proprietary. As a result, we cannot assure you that our means of protecting our proprietary rights will be adequate, and the infringement of such rights could have a material negative impact on our business and on our results of operations.

We have filed for U.S. and foreign patent applications and trademark registrations for our patents and trademarks. We may not be successful in obtaining these patents and trademarks, and we may be unable to obtain additional patent and trademark protection in the future. Furthermore, legal standards relating to the validity, enforceability and scope of protection of intellectual property rights are uncertain. It is possible that, despite our efforts, competitors or others will create and use products in violation of our patents and/or adopt service names similar to our service names or otherwise misappropriate our intellectual property. Such patent infringement or misappropriation could have a material adverse effect on our business. Any unauthorized production of our SDC-based products, whether in the U.S. or overseas, would or could reduce our own sales of SDC-based products, thereby reducing, perhaps significantly, our actual or potential profits. Adopting similar names and trademarks by competitors could lead to customer confusion. Any claims or customer confusion related to our trademarks could negatively affect our business.

Litigation may be necessary to enforce our intellectual property rights and protect our trade secrets. If third parties prepare and file applications in the U.S. or other countries that claim trademarks used or registered by us, we may oppose those applications and may be required to participate in proceedings before the regulatory agencies who determine priority of rights to such trademarks. Any litigation or adverse priority proceeding could result in substantial costs and diversion of resources, and could seriously harm our business and operating results.

If we are found to have violated the trademark, trade secret, copyright, patent or other intellectual property rights of others, such a finding could result in the need to cease use of a trademark, trade secret, copyrighted work or patented invention in our business and the obligation to pay a substantial amount for past infringement. It could also be necessary for us to pay a substantial amount in the future if the rights holders are willing to permit us to continue to use the intellectual property rights. Either having to cease use or pay such amounts could make us much less competitive and could have a material adverse impact on our business, operating results and financial condition.

To the extent that we operate internationally, the laws of foreign countries may not protect our proprietary rights to the extent as do the laws of the U.S. Many countries have a "first-to-file" trademark registration system. As a result, we may be prevented from registering or using our trademarks in certain countries if third parties have previously filed applications to register or have registered the same or similar trademarks. Our means of protecting our proprietary rights may not be adequate, and our competitors, or potential competitors, could independently develop similar technology.

We may become subject to product liability claims

As a business which manufactures and markets products for use by consumers and institutions, we may become liable for any damage caused by our products, whether used in the manner intended or not. Any such claim of liability, whether meritorious or not, could be time-consuming and/or result in costly litigation. Although we maintain general liability insurance, our insurance may not cover potential claims of the types described above and may not be adequate to indemnify for all liabilities that may be imposed. Any imposition of liability that is not covered by insurance or is in excess of insurance coverage could harm our business and operating results, and you may lose some or all of any investment you have made, or may make, in our common stock.

Litigation or the actions of regulatory authorities may harm our business or otherwise distract our management

Substantial, complex or extended litigation could cause us to incur major expenditures and distract our management. For example, lawsuits by employees, former employees, shareholders, partners, customers, or others, or actions taken by regulatory authorities, could be very costly and substantially disrupt our business. Such lawsuits or actions could from time to time be filed against the Company and/or or our executive officers and directors. Such lawsuits and actions are not uncommon, and we cannot assure you that we will always be able to resolve such disputes or actions on terms favorable to the Company.

Maintaining compliance with our obligations as a public company may strain our resources and distract management, and if we do not remain compliant our stock price may be adversely affected

Our common stock is registered under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). It is therefore subject to the information, proxy solicitation, insider trading and other restrictions and requirements of the SEC under the Exchange Act. The SEC continues to issue new and proposed rules, and complying with existing and new rules has resulted, and will continue to result, in the requirement for us to devote significant financial and other resources in order for us to maintain our status as a public company. In addition, in April 2008 we obtained a listing of our common stock on the NASDAQ Capital Market, adding the additional cost and administrative burden of maintaining such a listing. These additional regulatory costs and requirements will reduce our future profits or increase our future losses, and more management time and effort will be needed to meet our regulatory obligations than was needed prior to 2008.

We are required to evaluate our internal controls systems in order to allow management to report on our internal controls as required by Section 404 of the Sarbanes-Oxley Act. Our management is required to attest to, and have our Independent Registered Public Accounting Firm attest to, the adequacy of our internal controls. We are also required to file our annual and quarterly reports with the Securities and Exchange Commission ("SEC") on an accelerated basis. Recent SEC pronouncements suggest that in the next several years we may be required to report our financial results using new International Financial Reporting Standards, replacing GAAP, which would require us to make significant investments in training, hiring, consulting and information technology, among other investments. All of these and other reporting requirements and heightened corporate governance obligations that we face, or will face, will further increase the cost to us, perhaps substantially, of remaining compliant with our obligations under the Exchange Act and the Sarbanes-Oxley Act. In order to meet these incremental obligations, we will need to invest in our corporate and accounting infrastructure and systems, and acquire additional services from third party auditors and advisors. As a result of these requirements and investments, we will incur significant additional expenses and will suffer a significant diversion of management's time. There is no guarantee that we will be able to continue to meet these obligations in a timely manner, and we could therefore be subject to sanctions or investigation, or the delisting of our common stock, by regulatory authorities such as the SEC or the NASDAO Capital Market. Any such actions could adversely affect our financial results and the market price of our common stock, perhaps significantly.

Our publicly-filed reports are reviewed from time to time by the SEC, and any significant changes or amendments required as a result of any such review may result in material liability to us and may have a material adverse impact on the trading price of our common stock

The reports of publicly-traded companies are subject to review by the SEC from time to time for the purpose of assisting companies in complying with applicable disclosure requirements, and the SEC is required, pursuant to the Sarbanes-Oxley Act of 2002, to undertake a comprehensive review of a company's reports at least once every three years. SEC reviews may be initiated at any time. While we believe that our previously filed SEC reports comply, and we intend that all future reports will comply in all material respects with the published rules and regulations of the SEC, we could be required to modify, amend or reformulate information contained in prior filings as a result of an SEC review. Any modification, amendment or reformulation of information contained in such reports could be significant and result in material liability to us and have a material adverse impact on the trading price of our common

stock.

We are dependent on our management team, and the loss of any key member of this team may prevent us from achieving our business plan in a timely manner

Our success depends largely upon the continued services of our executive officers and other key personnel. Our executive officers and key personnel could terminate their employment with us at any time without penalty. We do not maintain key person life insurance policies on our executive officers or other employees, other than Michael L. Krall, our President and Chief Executive Officer. The policy we have on Mr. Krall would likely not provide a benefit sufficient to offset the financial losses resulting from the loss of Mr. Krall's future services. The loss of one or more of our executive officers or key employees could seriously harm our business, results of operations, financial condition, and/or the market price of our common stock. We cannot assure you that in such an event we would be able to recruit qualified personnel able to replace these individuals in a timely manner, or at all, on acceptable terms.

Because competition for highly qualified business development and bioengineering personnel is intense, we may not be able to attract and retain the employees we need to support our planned growth

To successfully meet our objectives, we must continue to attract and retain highly qualified business development and bioengineering personnel with specialized skill sets focused on the industries in which we compete, or intend to compete. Competition for qualified business development and bioengineering personnel can be intense. Our ability to meet our business development objectives will depend in part on our ability to recruit, train and retain top quality people with advanced skills who understand our technology and business. In addition, it takes time for our new personnel to become productive and to learn our business. If we are unable to hire or retain qualified business development and bioengineering personnel, it will be difficult for us to sell our products or to license our technology, and we may experience a shortfall in revenue and not achieve our anticipated growth.

Anti-takeover provisions under our charter documents and California law could delay or prevent a change of control and could also limit the market price of our stock

Certain provisions of our charter and by-laws may delay or frustrate the removal of incumbent directors and may prevent or delay a merger, tender offer, or proxy contest involving us that is not approved by our Board of Directors (the "Board"), even if such events may be beneficial to the interests of shareholders. For example, our Board, without shareholder approval, has the authority and power to issue all authorized and unissued shares of common stock which have not otherwise been reserved for issuance, on such terms as the Board determines. The Board could also issue 5,000,000 shares of preferred stock and such preferred stock could have voting or conversion rights which could adversely affect the voting power of the holders of our common stock. In addition, California law contains provisions that have the effect of making it more difficult for others to gain control of the Company.

The price of our common stock may be volatile, which may cause investment losses for our shareholders

Since our initial public offering in August 1996, the price and trading volume of our common stock have been highly volatile. The price has ranged from below \$1 per share to over \$8 per share, and the monthly trading volume has varied from under 200,000 shares to over 7.8 million shares. During the twelve months prior to December 9, 2009, the closing price of our common stock on any given day has ranged from \$1.50 to \$3.99 per share, and the monthly trading volume has varied from approximately 1.6 million shares to approximately 5.4 million shares. In the future, the market price of our common stock may be volatile and could fluctuate substantially due to many factors, including:

- actual or anticipated fluctuations in our results of operations;
- the introduction of new products or services, or product or service enhancements by us or our competitors;
- developments with respect to our or our competitors' intellectual property rights or regulatory approvals or denials;
  - announcements of significant acquisitions or other agreements by us or our competitors;
- the sale by us of our common or preferred stock or other securities, or the anticipation of sales of such securities;
  - sales or anticipated sales of our common stock by our insiders (management and directors);
    - the trading volume of our common stock, particularly if such volume is light;
      - conditions and trends in our industry;
      - changes in our pricing policies or the pricing policies of our competitors;
  - changes in the estimation of the future size and growth of our markets and, among other factors;
    - general economic conditions.

In addition, the stock market in general, the NASDAQ Capital Market, and the market for shares of novel technology and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, the market prices of bioscience companies have been unusually volatile in the last year, and many economists expect such unusual volatility to continue for the foreseeable future. These broad market and industry factors may materially harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market price of a company's securities, shareholder derivative lawsuits and securities class action litigation have often been instituted against that company. Such litigation, if instituted against the Company or our officers and directors, could result in substantial costs and a diversion of management's attention and resources. In addition, this volatility could adversely affect an investor's ability to sell shares of our common stock and/or the available price for such shares, and could result in lower prices being available to an investor if the investor wishes to sell their shares at any given time.

Our future capital needs are uncertain, and we may need to raise additional funds in the future which may not be available on acceptable terms or at all

Our capital requirements will depend on many factors, including, among other factors:

• acceptance of, and demand for, our products;

- the success of our strategic partners in developing and selling products derived from our technology;
  - the costs of further developing our existing, and developing new, products or technologies
    - the extent to which we invest in new technology, testing and product development;
      - the number and timing of acquisitions and other strategic transactions; and
  - the costs associated with the continued operation, and any future growth, of our business.

Our existing sources of cash and cash flows may not be sufficient to fund our future activities. As a result, we may need to raise additional funds, and such funds may not be available on favorable terms, or at all. Furthermore, if we issue equity or convertible debt securities to raise additional funds, our existing shareholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing shareholders. If we incur additional debt, it may increase our leverage relative to our earnings or to our equity capitalization. If we cannot raise funds on acceptable terms, we may need to scale back our expenditures through reductions in our workforce and operations, and we may not be able to develop or enhance our technologies and/or products, execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated consumer requirements.

We may not be able to maintain our NASDAQ listing

In April 2008, we obtained a listing for our common stock on the NASDAQ Capital Market. In order to maintain our listing, we will need to continue to meet certain minimum listing standards that include, or may include, our shareholders' equity, the market value of our listed or publicly held securities, the number of publicly held shares, our net income, a minimum bid price for our common stock, the number of shareholders, the number of market makers, and certain of our corporate governance policies. If we fail to maintain the standards required now or in future by the NASDAQ Capital Market, our common stock could be delisted from the NASDAQ Capital Market. Such delisting could cause our stock to be classified as "penny stock,", among other potentially detrimental consequences, any of which could significantly impact your ability to sell your shares or to sell your shares at a price that you may deem to be acceptable.

If outstanding options and warrants to purchase shares of our common stock are exercised, or if other remaining authorized shares of our common stock are issued, the interests of our shareholders could be diluted

We have approximately 8,186,922 shares of common stock reserved for issuance, which includes shares under equity compensation plans, vested and unvested options, and warrants. These shares have a weighted-average exercise price of approximately \$2.34. In addition, 7,479,790 authorized shares of our common stock remain available for future issuance under equity compensation plans or otherwise. The exercise of options and warrants, and the sale of shares underlying such options or warrants, could have an adverse effect on the market for our common stock, including the price that an investor could obtain for their shares. Investors may experience dilution in the net tangible book value of their investment upon the exercise of outstanding options and warrants granted under our stock option plans, and options and warrants yet to be granted or issued.

We may not be able to utilize all of, or any of, our tax net operating loss carry-forwards and our future after-tax earnings, if any, could be reduced

At October 31, 2009, we had federal and California tax net operating loss carry-forwards of approximately \$50,009,800 and \$39,871,800, respectively. Utilization of the net operating loss carry-forwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code as well as similar state provisions. These ownership changes may limit the amount of net operating loss carry-forwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 of the Internal Revenue Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups. Since the Company's formation, we have raised capital through the issuance of capital stock on several occasions (both before and after our initial public offering in 1996) which, combined with the purchasing shareholders' subsequent disposition of those shares, may have resulted in such an ownership change, or could result in an ownership change in the future upon subsequent disposition. While we believe that the Company has not experienced an ownership change, the pertinent tax rules related thereto are complex and subject to varying interpretations, and thus complete assurance cannot be provided that the taxing authorities would not take an alternative position.

In addition, our federal tax loss carry-forwards will begin expiring in the year ending July 31, 2010 unless previously utilized, and will completely expire in the year ending July 31, 2028. Between July 31, 2010 and July 31, 2012, \$3,323,800 of our federal net operating loss carry-forwards will expire, and the balance of our current federal net operating loss carry-forwards will expire between July 31, 2018 and July 31, 2028. Our California tax loss carry-forwards will begin to expire in the year ending July 31, 2014, and will completely expire in the year ending July 31, 2029. If we are unable to earn sufficient profits to utilize the carry-forwards by these dates, they will no longer be available to offset future profits, if any.

We are subject to tax audits by various tax authorities in multiple jurisdictions

From time to time we may be audited by tax authorities to whom we are subject. Any assessment resulting from such audits, if any, could result in material changes to our past or future taxable income, tax payable or deferred tax assets, and could require us to pay penalties and interest that could materially adversely affect our financial results.

We may never pay dividends

We have never paid any cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The future payment of dividends on our common stock, if any, is dependent on the discretion of our Board, our earnings, our financial condition and other business and economic factors which our Board may consider relevant.

Item 6. Exhibits

## A. Exhibits

The following Exhibits are filed as part of this report pursuant to Item 601 of Regulation S-K:

- 31.1 -- Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002\*
- 31.2 -- Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002\*
- 32.1 -- Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002\*
- 32.2 -- Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002\*
- \* Filed herewith.

## Signatures

Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**PURE Bioscience** 

By: /s/ Michael L. Krall Michael L. Krall

President / Chief Executive Officer (Principal Executive Officer)

December 10, 2009

By: /s/ Andrew J. Buckland

Andrew J. Buckland Chief Financial Officer (Principal Financial Officer)

December 10, 2009